UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF WISCONSIN

SCHWARZ PHARMA, INC.,
CIMA LABS, INC.,

Plaintiffs,

v. Case No. 02-C-0918

BRECKENRIDGE PHARMACEUTICAL, INC.,
and NAPEAN ENTERPRISES, INC.,

Defendants.

DECISION AND ORDER DENYING PLAINTIFF SCHWARZ PHARMA, INC.'S, MOTION FOR PARTIAL SUMMARY JUDGMENT (DOC. # 158), DENYING BRECKENRIDGE PHARMACEUTICAL, INC.'S, REQUEST FOR A CONTINUANCE, GRANTING SCHWARZ PHARMA, INC.'S, MOTION FOR SUMMARY JUDGMENT ON BRECKENRIDGE PHARMACEUTICAL, INC.'S, COUNTERCLAIMS (DOC. # 161), GRANTING BRECKENRIDGE PHARMACEUTICAL, INC.'S, MOTION FOR SUMMARY JUDGMENT ON COUNT I OF THE FIRST AMENDED COMPLAINT (DOC. # 165), DENYING BRECKENRIDGE PHARMACEUTICAL, INC.'S, MOTION FOR SUMMARY JUDGMENT ON ALL OTHER COUNTS (DOC. # 165)

Plaintiffs Schwarz Pharma Labs and CIMA Labs, Inc., developed a prescription drug called NULEV used to treat a variety of gastrointestinal and urological disorders, including Irritable Bowel Syndrome. NULEV is an orally disintegrating tablet (ODT) containing 0.125 mg of hyoscyamine sulfate. Schwarz asserts that defendants Breckenridge Pharmaceutical, Inc., and Napean Enterprises, Inc., collaborated with Best Formulations to create NEOSOL, an alleged "knock-off" of NULEV. The dispute has been contentious, and the parties have filed cross-motions for summary judgment, a motion for summary judgment on Breckenridge's counterclaims, volumes of supporting documents, and over twenty motions in limine or to strike. Many of the filings are duplicative, or

intertwined with issues presented elsewhere. This order will address the pending summary judgment motions. A separate order will issue regarding the motions in limine and final pretrial conference.

SUMMARY JUDGMENT STANDARD

Summary judgment is proper when "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c). A genuine issue of material fact exists only if "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248, 106 S. Ct. 2505, 2510, 91 L. Ed. 2d 202 (1986). In determining whether a genuine issue of material fact exists, the court construes all facts and reasonable inferences in a light most favorable to the non-moving party. *Id.* at 255. As such, on cross-motions for summary judgment, the court construes all the facts and reasonable inferences in favor of the party against whom the motion under consideration is made. *Tegtmeier v. Midwest Operating Eng'r Pension Trust Fund*, 390 F.3d 1040, 1045 (7th Cir. 2004). The party seeking summary judgment has the burden of establishing the lack of any genuine issue of material fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323, 106 S. Ct. 2548, 2552, 91 L. Ed. 2d 265 (1986). The existence of a factual dispute is not sufficient to defeat a summary judgment motion. *Butts v. Aurora Health Care, Inc* ., 387 F.3d 921, 924 (7th Cir. 2004). Instead, the non-moving party must present definite, competent evidence to rebut the summary judgment motion. *Id.*

PLAINTIFF SCHWARZ PHARMA, INC.'S, MOTION FOR PARTIAL SUMMARY JUDGMENT AND DEFENDANT BRECKENRIDGE PHARMACEUTICAL, INC.'S, MOTION FOR SUMMARY JUDGMENT

Cross motions for summary judgment are pending before this court. Breckenridge argues that the plaintiffs' Lanham Act claims, common law unfair competition and misappropriation, violations of Wis. Stats. § 100.18 and 100.182 and request for declaratory relief are preempted by the Food, Drug & Cosmetic Act (FDCA). Alternatively, Breckenridge submits that all statements it has made regarding NEOSOL are true, and that Schwarz has failed to meet the requirements of any unfair competition, copyright, or state law claim. Schwarz moves for partial summary judgment on its Lanham Act claims arguing that Breckenridge's advertisement and promotion of NEOSOL were literally false for the following reasons: (1) NEOSOL was not an ODT; (2) NEOSOL was not formulated to disintegrate within seconds after placement on the tongue; (3) NEOSOL did not contain 0.125 mg of hyoscyamine sulfate; and (4) NEOSOL was not equivalent to NULEV.

Findings of Fact

The court cannot set forth the proposed findings of fact without commenting on both parties' failure to properly authenticate documents or support their respective objections to proposed findings. For example, Schwarz attacks Breckenridge's Exhibit 9: the June 30, 2003, Declaration of Gary Callahan. Schwarz argues that portions of the declaration are contradicted by Callahan's prior deposition testimony, but Schwarz fails to attach pages 143, 147, 298 and 347 to Schwarz's Exhibit 10 for this court's review. Pages 143 and 147 are attached to a Breckenridge exhibit, but pages 298 or 347 are not part of the summary judgment record.

In addition, Schwarz attacks the documents attached to the Declaration of Callahan on the ground that they have not been properly authenticated. Yet none of the exhibits filed in support of Schwarz's motion for partial summary judgment or in opposition to Breckenridge's motion for summary judgment was attached to a declaration, affidavit or index. Aside from obvious evidentiary issues, the form of the submission requires speculation as to the location of the supporting document, its identity and source. To illustrate, Schwarz's Exhibit 19 is nineteen pages, and appears to have been produced in the Deposition of Gary Callahan in 2003 (it is not possible to discern the date of the deposition from the exhibit sticker). There is no reference to Exhibit 19 in the deposition transcript filed as Exhibit 9 and the exhibit contains selected pages only. While the first page of Exhibit 19 indicates that it is "Best Formulations Finished Product Release," Schwarz's proposed findings of fact cite to "Exhibit 19, NEOSOL Package Insert." (Schwarz Pharma, Inc.'s, Proposed Findings of Fact in Support of its Motion for Summary Judgment, p. 2, ¶ 7)

For purposes of resolving the pending motions, the court has reviewed all supporting documents filed by the parties, and has construed the findings in the light most favorable to the nonmoving parties. Objections to various exhibits and witnesses have been raised in various motions in limine filed after the briefing of the summary judgment motions, and will be addressed separately. Failure by both sides to comply with the federal civil and local rules have made it impossible to address the motions in any other manner.

The parties agree that plaintiff CIMA Labs, Inc., manufactures NULEV hyoscyamine sulfate orally disintegrating tablets for Schwarz. (Plaintiff's Ex. 2, Dep.

Behnken, pp. 17-18; Ex. 6, p. 116) Schwarz began marketing NULEV in March 2001. (Ex. 5, Decl. Losiniecki, ¶ 12; Ex. 6 Dep. Losiniecki, pp. 142-143)

Defendant Napean Enterprises, Inc., arranged with manufacturer, Best Formulations to produce and market NEOSOL. Napean supplied NEOSOL to Breckenridge. (Defendant's Ex. 16, Dep. Callahan, pp. 50, 96, 346)

NULEV, an ODT, contains 0.125 mg of hyoscyamine sulfate. (Plaintiff's Ex. 1, Decl. Behnken, ¶ 6) It is manufactured in compliance with current, good manufacturing practices, (Plaintiff's Ex. 1, Decl., Behnken ¶6), and is formulated to disintegrate within seconds after placement on the tongue. (Plaintiff's Ex. 5, Decl. Losiniecki, ¶11; Ex. 3, Decl. Siebert, ¶16)

Breckenridge claimed in commercial advertising and promotion that NEOSOL was an ODT and that NEOSOL contained 0.125 mg of hyoscyamine sulfate. (Plaintiff's Exs. 13, 14, 15, 17, and 19) In its package insert, Breckenridge also claimed that NEOSOL was formulated to "disintegrate within seconds after placement on the tongue." (Plaintiff's Ex. 9) Finally, Breckenridge used the term "reference" in comparing NEOSOL to NULEV. (Plaintiff's Ex. 13, 14, 24) In commercial advertising and promotion, Breckenridge described NEOSOL as an ODT containing 0.125 mg of hyoscyamine sulfate and described NULEV as the "reference" product. (Plaintiff's Exs. 9, 13, 14, 17, 24)

Lane Brunner, Ph.D., an expert for Schwarz, reports that "the FDA has developed a working specification which recommends that an orally disintegrating tablet should disintegrate within one minute in the standard USP disintegration test." (Defendant's Exhibit 7) However, after Breckenridge moved for summary judgment, Schwarz filed a November 23, 2004, Declaration of Barry Behnken, stating that the USP

disintegration test was only recently adopted as a working specification for ODTs and is too aggressive for some ODTs like NULEV because they disintegrate too quickly to obtain meaningful test results. (Plaintiff's 2004 Decl. Behnken, ¶¶ 6,7)

Gary Callahan, Vice President of Technical and Regulatory Affairs for Best Formulations, testified in his deposition that they did not have any stability testing or process valediction completed at the time Breckenridge sent its first shipment of NEOSOL to Crandall Associates. (Plaintiff's Ex. 10, pp. 126, 268) In addition, after conducting an inspection of Best in July and August of 2002, the FDA issued to Best an FDA Form 483 Report, dated August 7, 2002. (Plaintiff's Ex. 28) The Report included the observation that Best's written stability program for drug products did not include reliable, meaningful and specific test methods. (Plaintiff's Ex. 28) Further, the Report included the observation that Best had not conducted or completed process validation for NEOSOL. (Plaintiff's Ex. 10, Dep. Callahan, pp. 304-308; Ex. 28)

Although NULEV is not the subject of an approved New Drug Application, it is registered with the FDA and covered by a compliance policy guide. (Defendant's Ex. 8, p. 141) Both NEOSOL and NULEV lack dyes and are white in color. (Defendant's Exs. 6, 14; Decl. Arent, Exs. 20, and 22) There is nothing unique or distinctive in the use of a round tablet, and each product is packaged for wholesalers, distributors, and pharmacists in plastic bottles of a standard, generic, shape. (Decl. Arent, Exs. 20-22) However, the bottles utilized by Breckenridge are larger than those utilized by plaintiff. (*Id.*)

Finally, the certificate of copyright registration obtained by Schwarz relating to the package insert is a derivative work. (Defendant's Ex. 15) Schwarz is the exclusive

owner of all copyrights in its package insert including, without limitation, the content, expression, text, and arrangement. (Amended Complaint, ¶ 91)

Conclusions of Law

Breckenridge first moved for summary judgment on CIMA's claim that Breckenridge and Best infringed CIMA's Patent 6,024,981 during the production of NEOSOL. Schwarz is not pursuing a patent claim against Breckenridge, and it is axiomatic that the court cannot enter summary judgment on a claim that does not exist. To the extent that CIMA is pursing a claim, the joint final pretrial report indicates that CIMA and Breckenridge have resolved their claims. The parties shall submit an appropriate stipulation of dismissal, and Breckenridge's motion for summary judgment on CIMA's patent claim will be denied as moot.

Next, the court turns to the issue of preemption. According to Breckenridge, preemption should be applied expansively because all of the claims require the "interpretation and enforcement of the FDCA and the regulations promulgated thereunder, and fall within the exclusive domain of the FDA." (Breckenridge's Corrected Brief in Support of Motion for Summary Judgment, p. 10) Breckenridge's theory is premised on statutory language that the right to enforce the provisions of the FDCA lies exclusively within the government's domain, under either the FDA or the Department of Justice. 21 U.S.C. § 337.

Rather than addressing each count or otherwise identifying the relevant sections of the FDCA or its related regulations, Breckenridge cites selectively to the following allegations in plaintiffs' amended complaint:

- The FDA has not determined that NEOSOL is therapeutically equivalent to NULEV. (Plaintiff's First Amended Complaint, ¶ 30)

- CIMA manufactures NULEV in compliance with FDA current good manufacturing practices. (Plaintiff's First Amended Complaint, ¶ 20)

- Breckenridge, Best and Napean manufacture and /or market a "knock-off" version of NULEV. (Plaintiff's First Amended Complaint, ¶¶ 23-28)

- Breckenridge has wrongfully compared NEOSOL to NULEV or wrongfully implied reference listed drug status by use of the term "reference" in advertisements for NEOSOL. (Plaintiff's First Amended Complaint, ¶ 51)

- NEOSOL is not generic or equivalent to or substitutable for NULEV. (Plaintiff's First Amended Complaint, ¶¶ 29-38)

- NEOSOL is not therapeutically or pharmaceutically equivalent nor bioequivalent to NULEV. (Plaintiff's First Amended Complaint, ¶¶ 33-35)

- The Defendants fabricated the expiration dating for NEOSOL. (Plaintiff's First Amended Complaint, ¶ 51)

The preemption issue cannot be analyzed in this manner. Rather, each count needs to be examined to determine the scope of the claim and the context in which the allegations are made. For example, in Count I, Schwarz alleges that it is entitled to a declaration that it is unlawful for pharmacists to substitute NEOSOL for prescriptions of NULEV. Count II charges that defendants' promotional claims about NEOSOL are literally or impliedly false and misleading (Lanham Act). Count III asserts unfair competition under the Lanham Act to the extent that defendants "deliberately attempted to formulate NEOSOL to be indistinguishable from NULEV in style, coloration, appearance, impression,

taste, packaging and labeling." Count IV contends that defendants have "either directly or indirectly, each made, published, disseminated and/or circulated false, deceptive and misleading statements, representations and advertisements concerning NEOSOL with the intent of selling, distributing, and increasing the consumption of and interest in NEOSOL in violation of Wis. Stat. §§ 100.18 and 100.182." Count V alleges common law unfair competition based on "false and misleading explicit and implicit representations to drug wholesalers, distributors, drug store chains, pharmacists and others, concerning NEOSOL." Count VI asserts misappropriation and Count VII charges a violation of the Federal Copyright Act arising from Schwarz's packaging insert

The Lanham Act provides a private remedy to a plaintiff harmed by "commercial advertising or promotion" that "misrepresents the nature, characteristics, qualities or geographic origin of his or her or another person's goods, services, or commercial activities." 15 U.S.C. § 1125(a)(1)(B). Similarly, Wisconsin law prohibits false and misleading statements. Wis. Stats. §§ 100.18 and 100.182. In contrast, the FDCA "'is not focused on the truth or falsity of the advertising claims' but on protecting the public interest in safety and efficacy" of food, drugs, and cosmetics and does not allow for private rights of action. *See Mylan Laboratories, Inc., v. Matkari*, 7 F.3d 1130, 1139 (4th Cir. 1993) (citing *Sandoz Pharmaceuticals Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222, 230 (3rd Cir. 1990)). Private rights of action are not allowed under the FDCA, and the text is explicit: "all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States." 21 U.S.C. § 337(a).

When and if a claim strays "too close to the exclusive enforcement domain of the FDA," it cannot stand. *Summit Technology, Inc., v. HighLine Med. Instruments Co.,*

Inc., 922 F. Supp. 299, 306 (C.D. Cal. 1996). Such claims would "allow a private litigant to interfere with the FDA's own investigatory time-table and prosecutorial decision-making." *Summit Technology, Inc., v. HighLine Med. Instruments Co., Inc.,* 933 F. Supp. 918, 934 (C.D. Cal. 1996). However, the mere FDA regulation of a term does not necessarily bar all Lanham Act claims that pertain to that term. *See Summit*, 933 F. Supp. at 933 ("[F]alse statements are actionable under the Lanham Act, even if their truth may be generally within the purview of the FDA."); *Ethex Corp. v. First Horizon Pharmaceutical Corp.*, 228 F. Supp. 2d 1048, 1055 (E.D. Mo. 2002) ("False statements, however, are actionable under the Lanham Act even if they involve FDA-regulated products."). Ultimately, there is no "single, bright-line test to distinguish sustainable from non-sustainable claims." *Healthpoint*, *Ltd. v. Stratus Pharmaceuticals, Inc.*, 273 F. Supp. 2d 817, 837 (W.D. Tex. 2001).

Several courts have addressed the issue of preemption where one pharmaceutical company has accused another of manufacturing and marketing a "knock-off" drug. First, in *Mylan,* 7 F.3d at 1138, the complaint alleged that defendants falsely represented their product was the "bioequivalent to its innovator counterpart and other approved generic equivalents;" "that the product was entitled to an AB rating" from the FDA; or that the product was the "generic alternative" to the innovator drug. *Id.* In addition, the plaintiff claimed that by placing its drugs on the market, defendants were falsely representing that its drugs had been approved by the FDA. *Id.* The Fourth Circuit Court of Appeals drew a distinction between the two types of claims, and allowed the plaintiff to proceed on claims regarding bioequivalence or generic equivalence. *Id.*, 7 F.3d at 1138-39. Those claims involved a statement or representation by the defendants that led

consumers to believe that a drug is the generic or equivalent. *Id.* On the other hand, plaintiff's false-approval claim that merely placing the drug on the market implied FDA approval was nothing more than an attempt to enforce the FDCA and its corresponding regulations. *Id.*

More recently, Judge Frank in the District Court of Minnesota followed the reasoning of *Mylan* and allowed the plaintiff to proceed on claims for falsely stating or implying that a drug is a "generic, "comparable," "alternative," or "equivalent." *Solvay Pharmaceuticals, Inc., v. Global Pharmaceuticals and Impax Laboratories, Inc.,* 298 F. Supp. 2d 880 (D. Minn. 2004). The court reasoned that the plaintiff had identified allegedly false statements made by the defendant not related to FDA approval or the lack thereof. *Id.*, 298 F. Supp. 2d at 884. Neither the plaintiff nor defendant was listed in the FDA's Orange Book. *Id.* Therefore, FDA approval was not required to substitute the products or to make a determination of bioequivalence or therapeutic equivalence. *Id.*

Following the reasoning of *Mylan and Solvoy*, this court finds that none of the claims at issue is subject to dismissal with the following exception. Count I: Request for Declaratory Relief asks this court to declare that because NEOSOL is not listed as a therapeutic equivalent, has not been proven to be a therapeutic equivalent, and is not a therapeutic equivalent, it is unlawful for pharmacists to substitute NEOSOL for prescriptions of NULEV in Pharmaceutical Equivalence, Therapeutic Equivalence or Orange Book States. (First Amended Complaint, ¶¶ 44-49)

The defendant in *Ethex*, 228 F. Supp. 2d at 1059, y invited the court "to issue a nationwide declaratory judgment stating that 'because KV's products have not been

proved to be equivalent to PRENATE, it is unlawful for KV to suggest or insinuate to pharmacists that they can substitute KV's products for prescriptions of PRENATE in states that limit substitution to pharmaceutically or therapeutically equivalent drugs.'" In declining this invitation, the court set forth its preemption analysis and further reasoned:

> Defendants ask this Court to interpret the pharmacy laws of the fifty states and engage in a mass judicial fiat by adjudicating the propriety of Plaintiffs' marketing practices without any word from a single pharmaceutical board .... This is the sort of complex issue of state law that should be left to the various pharmacy boards and courts of the respective states.

Ethex, at 1059. While the defendant in *Ethex* asked the court to declare unlawful the plaintiff's marketing practices, Schwarz goes a step further and requests the court to declare unlawful the acts of pharmacists in all Orange Book, Therapeutic Equivalence, or Pharmaceutical states. Aside from any preemption concerns, this court cannot make such declaration against entities who are not parties to this suit. *See Solvay,* 298 F. Supp. 2d at 887. For these reasons, defendant's motion for summary judgment seeking dismissal of Count I will be granted.

With respect to the remaining claims, Breckenridge has failed to identify any section of the FDCA or its accompanying regulations that the court would be required to interpret or apply. In fact, Schwarz's expert states in his report that neither the NULEV or NEOSOL products has been listed in the Orange Book and there is no record of the FDA evaluating the two products for pharmaceutical equivalence. (Defendant's Ex. 7) In its brief, Breckenridge points out that the "FDA has not requested the submission of evidence regarding whether NULEV and NEOSOL are pharmaceutically equivalent, bioequivalent, therapeutically equivalent, or whether NEOSOL is in any respect a 'reference' to NEOSOL

[sic], or whether NEOSOL is an 'equivalent' of NULEV." (Breckenridge's Corrected Brief in Support of Motion for Summary Judgment, p. 12) In the absence of any FDA ruling or ongoing investigation, there is little chance that the court will usurp the role of the FDA.

It is remarkable that Breckenridge concedes that Schwarz's claims do not run afoul of the FDA's jurisdiction if Schwarz limits itself to the truth or falsity of the statements made in advertising. "To hold to the contrary would mean that an administrative scheme could eviscerate a Lanham Act or related common law claim over which the agency has no jurisdiction." *Healthpoint*, 273 F. Supp. 2d at 792-93. Accordingly, the court will allow Schwarz to proceed on all remaining claims to the extent that it is not seeking the interpretation or direct application of any FDA regulation. *See Grove Fresh Distributors, Inc., v. The Flavor Fresh Foods, Inc.*, 720 F. Supp. 714, 715 (N.D. Ill. 1989) (allowing a Lanham Act claim to proceed where the plaintiff could rely upon evidence of a market definition without interpreting a FDA regulation).

Next, both parties move for summary judgment on the Lanham Act claims. To establish a claim under the false or deceptive advertising prong of § 43(a) of the Lanham Act, a plaintiff must prove: (1) a false statement of fact by the defendant in a commercial advertisement about its own or another's product; (2) the statement actually deceived or has the tendency to deceive a substantial segment of its audience; (3) the deception is material, in that it is likely to influence the purchasing decision; (4) the defendant caused its false statement to enter interstate commerce; and (5) the plaintiff has been or is likely to be injured as a result of the false statement, either by direct diversion of sales from itself to defendant or by a loss of goodwill associated with its products. *Hot*

Wax, Inc., v. Turtle Wax, Inc., 191 F.3d 813, 819 (7th Cir. 1999) (citing *B. Sanfield, Inc., v. Finlay Fine Jewelry Corp*., 168 F.3d 967, 971 (7th Cir.1999)).

If such a statement is literally false, a plaintiff does not need to show actual deception or likelihood of deception. *Hot Wax*, *Inc.,* 191 F.3d at 820. To determine whether a particular representation is literally false, it must be analyzed with its full context. *United Industries Corp. v. Clorox Co.*, 140 F.3d 1175, 1180 (8 th Cir. 1998) (citing *Rhone-Poulenc Rorer Pharm., Inc., v. Marion Merrell Dow, Inc.*, 93 F.3d 511, 516 (8th Cir. 1996); *Southland Sod Farms v. Stover Seed Co.*, 108 F.3d 1134, 1139 (9th Cir. 1997)); *Avis Rent A Car Systems, Inc., v. Hertz Corp.*, 782 F.2d 381, 385 (2nd Cir. 1986). However, if the statement is literally true or ambiguous, "a plaintiff must prove that the statement is misleading in context by demonstrated actual consumer confusion." *Hot Wax*, 191 F.3d at 820 (citing *B. Sanfield*, 168 F.3d at 971-72). Consumer confusion is a question of fact. *See Scandia Down Corp. v. Euroquilt, Inc.*, 772 F.2d 1423, 1427-28 (7th Cir. 1985).

In its motion for summary judgment, Breckenridge argues that the NEOSOL claims of an oral disintegrating tablet and .125 mg. hyoscyamine sulfate are literally true whereas Schwarz maintains that all four claims, including that NEOSOL was formulated to dissolve within seconds and that NEOSOL was an equivalent, are false. The court, having reviewed all the evidence finds that neither party is entitled to summary judgment on the Lanham Act claims, as illustrated above, because there are genuine issues of material fact as to whether the claims are false.

Whether NEOSOL is an ODT is disputed. The FDA Center for Drug Evaluation and Standards' Data Standards Manual defines an ODT as a "solid dosage form containing medicinal substances which disintegrates rapidly, usually within a matter of seconds, when placed upon the tongue." (Plaintiff's Ex. 4) In laboratory tests under the direction of Barry Behnken, the Vice President of New Products for Schwarz, NEOSOL took an average of over six minutes to dissolve and no NEOSOL tablet took less than five minutes to dissolve. (Plaintiff's Ex. 1, Decl. Behnken, ¶¶ 18, 20; Ex. 3, Decl. Siebert, ¶¶ 18-21)

However, the testing consisted of both USP testing and a combination of Schwarz testing and CIMA testing. During his deposition, Behnken testified as follows:

> Q: For disintegration, the next line after "wait," under it, it says "USP," and then to the right it says "30 seconds."
> A: Yes, that's –
> Q: What is that?
> A: That's the result of the disintegration test using the USP apparatus for disintegration described in the section we previously discussed.

(Doc. #168, Ex. 8, Dep. Behnken p. 41) This would be consistent with the USP disintegration standard referenced by Schwarz's expert, Lane J. Brunner, Ph.D., in his initial report:

> NULEV tablets were formulated as orally disintegrating tablets. This type of tablet formulation is not intended to be swallowed whole, but are designed specifically to rapidly disintegrate when placed in the mouth (e.g. on the tongue). Orally disintegrating tablets are a relatively new dosage form, and, to date, no USP specifications for disintegration times have been established. In order to address this deficiency, the FDA has developed a working specification for the disintegration time of an orally disintegrating tablet using the current USP disintegration apparatus. The definition that the FDA has entered into its Data Standards Manual indicates that the

> product disintegrates rapidly, usually within seconds when placed on the tongue. The FDA recommendation is that the tablet should disintegrate within 1 minute in the standard USP disintegration testing.

(Doc. #168, report of Plaintiff's Expert Lane Brunner, PhD, ¶ 10) Although Behnken later filed a declaration that the USP test is not appropriate for ODTs and that the USP tests were simply not correct, there is a conflict in the testimony that cannot be resolved at this time.

Schwarz cites to other evidence that is equally conflicting. For example, Gary Callahan, Vice President for Technical and Regulatory Affairs for Best Formulations, testified in his deposition that Best "did not intend to make an ODT. We were told to make it dissolve in the mouth within a certain period of time." At the same time, Callahan testified that Best was told to make it dissolve within the mouth in "a minute or less, if we could." (Plaintiff's Ex. 10, Dep. Callahan, p. 59)

With respect to statements by Breckenridge that NEOSOL contained "hyoscyamine sulfate 0.125 mg" (Plaintiff's Exs, 9, 14, 15), Schwarz has submitted assay testing results (conducted by Schwarz), showing that NEOSOL tablets contain an average of 0.140 mg of hyoscyamine sulfate or approximately 12% more than NEOSOL's label claim. (Plaintiff's Ex. 1, Decl. Behnken, ¶ 15) The range of the active ingredient found in NEOSOL ranged from 82.6% of label claim to 163.2% of label strength. (Plaintiff's Ex. 1, Decl. Behnken, ¶ 16) Callahan testified that NEOSOL was manufactured with a deliberate overage of active ingredient (Dep. Callahan, pp. 285, 288), and batch record sheets reveal that NEOSOL was formulated to contain 0.140 mg of hyoscyamine sulfate. (Plaintiff's Ex.

18, BF00200; Ex. 19, BF00218; Ex. 20, BF00236; Ex. 21, BF00266; Ex. 23, BF00307; Ex. 22, BF00285)

Nevertheless, Breckenridge cites tests from independent laboratories concluding that NEOSOL contains 0.125 mg. of hyoscyamine sulfate and that NEOSOL was formulated to disintegrate or dissolve on the tongue within seconds. In an assay determination of the amount of active ingredient in randomly selected batches, NEOSOL fell within the USP standards. (Defendant's Exs. 8, 9, 10, and 11)

Schwarz has attacked all of the independent results as "suspicious and unreliable" whereas Breckenridge argues that Schwarz's testing was conducted in anticipation of litigation without the use of an independent laboratory. At this stage, their differences cannot be resolved as a matter of law.

Schwarz has moved for summary judgment on its remaining Lanham Act claim that Breckenridge used the term "reference" in comparing NEOSOL to NULEV. (Plaintiff's Ex. 14; Ex. 24, BR0107, BR0117, BR0457, BR0465) According to Schwarz, "reference" is a term the FDA uses to describe a brand name drug for which there is a generic substitute. Laurence Runsdorf, President of Breckenridge, testified as follows:

> Q: Have you represented it to the marketplace, either to pharmacy chains, wholesalers or distributors that your product NEOSOL is pharmaceutically equivalent to NULEV?
>
> A. We have not used those words.
>
> Q. Have you conveyed the meaning to any customer, including pharmacies, wholesalers, distributors or anyone else that your product NEOSOL is pharmaceutically equivalent to NULEV?
>
> A. Yes.

(Plaintiff's Ex. 7, Dep. Runsdorf, pp. 23-24)

Schwarz argues that NEOSOL did not meet the same standards as NULEV because NULEV is manufactured in compliance with the FDA current good manufacturing practices. (Decl. Behnken, ¶ 6) There was no stability testing for the first lot of NEOSOL, and process validation had not been completed during the first year of marketing NEOSOL. (Plaintiff's Ex. 10, Dep. Callahan, pp. 245-46, 267-68, 320-21) Moreover, the FDA noted "significant deviations from the Current Good Manufacturing Practice for Finished Pharmaceuticals Regulations" in a warning letter issued to Best on October 29, 2002. (Plaintiff's Ex. 26)

Schwarz is asking the court to rule as a matter of law that the use of the term "reference" is literally false. However, the meaning of "reference" and the message that it conveys are in dispute. There is no advertising in the record that makes the statement that NEOSOL is a pharmaceutically equivalent or bioequivalent of NULEV. Further, there is a genuine issue of material fact as to whether NEOSOL is the equivalent of NULEV. Consequently, Schwarz's motion for partial summary judgment on the Lanham Act claims will be denied.

Breckenridge has moved for summary judgment on Count III: Violation of Lanham Act Section 43(a)(Unfair Competition). Breckenridge asserts that Count III is nothing more than a claim of trade dress infringement, which is negated by the "common, generic, nature of the NULEV tablet design and packaging." To this end, NEOSOL and NULEV are small, round, white, beveled edged tablets. Breckenridge asserts that there is nothing unique about the tablet, and that the bottles used by Breckenridge are

significantly larger than those utilized by Schwarz. Moreover, Breckenridge argues that neither NULEV nor NEOSOL is marketed to the public at large.

Schwarz accuses Breckenridge of mischaracterizing the allegations in Count III, which is labeled as a claim for unfair competition. Schwarz points out that the words "trade dress" never appear in Count III. At the same time, Schwarz offers that "defendants deliberately attempted to formulate NEOSOL to be indistinguishable from NULEV in style, coloration, appearance, impression, taste, packaging, and labeling." (First Amended Complaint, ¶ 60) "Defendant's use of NEOSOL constitutes deliberate and willful copying of Schwarz's NULEV. Furthermore, in marketing or promoting NEOSOL, Breckenridge falsely represented or implied that NEOSOL is equivalent to or may be freely substituted for NULEV." (First Amended Complaint, ¶ 61)

Section 43(a), 15 U.S.C. § 1125(a) is one of the few provisions of the Lanham Act that goes beyond trademark protection. *Dastar Corp. v. Twentieth Century Fox Film Corp.*, 539 U.S. 23, 29, 123 S. Ct. 2041, 156 L. Ed. 2d 18 (2003). The Act provides:

> Any person who, on or in connection with any goods or services, or any container for goods, uses in commerce any word, term, name, symbol, or device, or any combination thereof, or any false designation of origin, false or misleading description of fact, or false or misleading representation of fact, which (A) is likely to cause confusion or to cause mistake, or to deceive as to the affiliation, connection, or association of such person with another person, or as to the origin, sponsorship, or approval of his or her goods, services, or commercial activities by another person, or (B) in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services or commercial activities, shall be liable in a civil action by any person who believes that he or she is likely to be damaged by such act.

15 U.S.C. § 1125(a)(1). However, § 43(a) "'does not have boundless application as a remedy for unfair trade practices.'" *Dastar*, 539 U.S. at 29 (quoting *Alfred Dunhill, Ltd. v. Interstate Cigar Co.,* 499 F.2d 232, 237 (2nd Cir. 1974)). "Because of its inherently limited wording, § 43(a) can never be a federal 'codification' of the overall law of 'unfair competition,'" *McCarthy,* Trademarks and Unfair Competition, § 27:7, p. 27-14 (4th Ed. 2002), but can only apply to certain unfair trade practices prohibited by its text. *Dastar,* 539 U.S. at 29.

Schwarz's efforts to distance itself from a trade dress claim are somewhat confusing. To the extent that Schwarz has an unfair competition claim independent of any trade dress theory, it is based on assertions that Breckenridge copied various aspects of NULEV and made misrepresentations to falsely represent that NEOSOL is an equivalent. This appears to be yet another claim of unfair competition/false advertising claim on which Schwarz may proceed. This issue will be revisited at the time of the final pretrial conference.

Breckenridge next contends that the copyright claims fail on the ground of an implied license. The Hatch-Waxman Act Amendments to the FDCA require virtually identical copying of package insert materials. They require that labeling of a generic drug must be "the same as the labeling approved for the pioneer drug." 21 U.S.C. § 355(j)(2)(A)(v). Hence, a pioneer drug manufacturer that holds a copyright "must be understood to grant an implied, nonexclusive license when it submits materials as proposed labeling for FDA approval." (Breckenridge Reply Brief in Support of Motion for Summary Judgment, p. 12)

Implied licenses will be found "only in 'narrow' circumstances where one party 'created a work at the [other's] request and handed it over, intending that [the other] copy and distribute it.'" *SmithKline Beecham Consumer Healthcare, L.P. v. Watson Pharms.*, Inc., 211 F.3d 21, 25 (2d Cir. 2000). Faced with an implied license claim, the Second Circuit Court of Appeals held that it is not clearly a defense in a case where a producer of a generic drug copies a product label. *SmithKline*, 211 F.3d at 25 (2d Cir. 2000). Rather, the Hatch-Waxman Act requires that producers of generic drugs use the same labeling as was approved for and used in the sale of the pioneer drug even if it has been copyrighted. *Id.* In *Smithkline*, the defendants obtained approval from the FDA to sell a competing generic nicotine gum product and were directed by the FDA to use labeling almost identical to the plaintiff's copyrighted guide and audio tape. Plaintiff filed a copyright action, but the FDA reported to the district court that such a requirement is consistent with the Hatch-Waxman Amendments to the Federal Food, Drug and Cosmetic Act, see Drug Price Competition and Patent Term Restoration Act of 1984 § 101, 21 U.S.C. § 355(j) ("Hatch-Waxman Amendments"). *Id.*, 211 F.3d at 23.

Here, there is insufficient information in the record to conclude that the Hatch-Waxman Amendments apply. Without citation, Breckenridge states that the FDA enforces these requirements whether or not the drugs are listed in the Orange Book. There are no findings of fact regarding what, if anything, Breckenridge has filed with the FDA. According to Breckenridge, neither NULEV nor any other drug comprising the plaintiff's Levsin line of hyoscyamine sulfate product has actually been approved by the FDA. Moreover, the FDA has not requested the "submission of evidence regarding whether NULEV and NEOSOL are pharmaceutically equivalent, bioequivalent, therapeutically equivalent, or

whether NEOSOL is in any respect a "reference" to NEOSOL, or whether NEOSOL is an "equivalent" of NULEV. (Breckenridge Corrected Brief in Support of Motion for Summary Judgment, p. 12) Further, Breckenridge states that NULEV is neither "an FDA approved brand pursuant to an FDA nor an FDA approved equivalent pursuant to an ANDA" as was the case in *Smithkline.* (Response Brief of Breckenridge to Schwarz Motion for Partial Summary Judgment, p. 6) Hence, this record does not establish that the FDA mandated the form of copying before this court.

The aforementioned observations are important because there is no evidence that Breckenridge filed anything with the FDA to bring it within the scope of the Hatch-Waxman Act. Rather, this is a case where the defendant is accused of rushing a product to the market without proper testing, passing off the product as a generic when it is not even the equivalent, and confusing wholesalers and pharmacists by almost verbatim copying of the package insert (with NULEV and Schwarz crossed out and "this product" and "Best Formulations" inserted). Therefore, genuine issues of material fact preclude summary judgment dismissing copyright claims on the ground of implied license.

Breckenridge further attacks the common law unfair competition and misappropriation claims on public policy grounds. Breckenridge believes that the lawsuit is nothing more than an attempt to gain a competitive advantage with other companies who have entered the market for hyoscyamine sulfate prescription drugs. In support, Breckenridge cites a 1943 case from the Second Circuit Court of Appeals for the general proposition that "there is a basic public policy, deep rooted in our economy and respected by the courts, resting on the assumption that social welfare is best advanced by free competition." *Eastern Wine Corp. v. Winslow-Warren, Ltd.*, 137 F.2d 955 (2nd Cir. 1943),

cert. denied, 320 U.S. 758. However, in the same paragraph, the Second Circuit wrote: "[T]he privilege afforded by good-faith competition is limited by other conflicting public policy considerations, including that of discouraging certain kinds of business practices regarded as unfair; and among such unfair practices are those which mislead consumers even to their pecuniary benefit." *Id.* Dismissal of this argument requires little discussion. With due regard for the facts in dispute, this court cannot decide as a matter of law that Schwarz is attempting to create a monopoly in the hyoscyamine sulfate prescription drug market.

Finally, Breckenridge argues that Schwarz cannot meet its burden with respect to its claims under Wis. Stat. § 100.18 and 100.182. The elements of a claim under Wis. Stat. § 100.18 are: (1) the defendant advertised the product; (2) the advertising was misleading; and (3) the plaintiff suffered pecuniary loss as a result of the misleading advertising. Wis. Stat. § 100.18. Similarly, section 100.182 provides:

> (2) No person may advertise the availability of any drug or publish or circulate such an advertisement with the intent of selling, increasing the consumption of or generating interest in the drug if the advertisement contains any untrue, deceptive or misleading representations material to the effects of the drug.

While Breckenridge repeats the arguments it raised with respect to the Lanham Act, there is a genuine issue of material fact as to whether the claims at issue were "untrue, deceptive or misleading. Consequently, Breckenridge's motion for summary judgment will be denied on this count.

PLAINTIFF SCHWARZ PHARMA, INC.'S, MOTION FOR SUMMARY JUDGMENT ON BRECKENRIDGE'S COUNTERCLAIMS

In its counterclaims, Breckenridge charges that Schwarz tortiously interfered with contracts and prospective contract relationships, engaged in false advertising in violation of the Lanham Act, and violated Wis. Stats. §§ 100.18 and 100.182. Schwarz filed a motion for summary judgment on Breckenridge's counterclaims arguing that there is no evidence to support these claims. Because this court agrees that Breckenridge has not met its burden, the court will grant the summary judgment motion and dismiss the counterclaims.

First, Breckenridge is lacking an essential element for a claim under the Lanham Act. Section 43(a) covers only "commercial advertising or promotion". *Sanderson v. Culligan Intern. Co.*, 415 F.3d 620, 624 (7th Cir. 2005); *First Health Group Corp. v. BCE Emergis Corp.*, 269 F.3d 800, 803 (7th Cir. 2001). The Seventh Circuit has defined "commercial advertising or promotion" as follows:

> Advertising is a form of promotion to anonymous recipients, as distinguished from face-to-face communication. In normal usage, an advertisement read by millions (or even thousands in a trade magazine) is advertising, while a person-to-person pitch by an account executive is not. So we have held in a series of disputes that require a definition of "advertising injury" under insurance policies.... Advertising is a subset of persuasion and refers to dissemination of prefabricated promotional material.

First Health Group, 269 F.3d at 803-04 (citations and internal quotation marks omitted).

Breckenridge relies exclusively upon statements said to have been made by two Schwarz representatives: Rebecca Recard and Richard Losiniecki. However, Rebecca Recard's alleged statements regarding NEOSOL were directed to a single pharmacist, who

worked at the Medicine Shoppe in Henderson, North Carolina. (Schwarz Ex. 1, Dep. Runsdorf, p. 207) The only testimony to support this is Rundsdorf's deposition testimony of what he recalls of a conversation with a pharmacist who allegedly spoke to Recard. (Dep. Runsdorf, p. 207) This is inadmissible hearsay, and a statement to a single pharmacist is not a statement made in commercial advertising.

Second, Losiniecki testified in his deposition that he made statements to three pharmaceutical wholesalers (Amerisource Bergen, Cardinal Distribution, and McKesson Corporation) in October/November 2002 at a trade convention. (Breckenridge Ex. 17, Dep. Losiniecki, pp. 152, 155, 156, 157) Losiniecki recalls asking them if they had bought NEOSOL, asking if it was listed as a generic, and telling these individuals that Schwarz was in litigation with Breckenridge. (*Id.*, at p. 152) Losiniecki thinks he told them that it is the position of Schwarz that you cannot substitute NEOSOL for NULEV and that there was Lanham Act litigation surrounding NEOSOL. (*Id.,* at p. 155)

Breckenridge has failed to produce any evidence contradicting the testimony of Losiniecki, and there is no evidence that his statements were false. Schwarz and Breckenridge have been in litigation since 2002, and it is Schwarz's position that one cannot substitute NEOSOL for NULEV. Further, each statement or communication was person-to-person and not the dissemination of "prefabricated promotional materials" to anonymous recipients as required under the Lanham Act. *First Health Group*, 269 F.3d at 803-04; *see also Sanderson,* 415 F.3d at 624.

Similarly, a claim for tortious interference fails because Breckenridge has no competent evidence to support this type of claim. A tortious interference claim requires a showing that (1) the injured party had an actual or prospective contractual relationship with

a third party; (2) the defendant interfered with the contract or the prospective contract; (3) the interference was intentional; (4) there is a causal connection between the interference and the damages; and (5) the defendant was not privileged to interfere. *Minnesota Mining & Mfg. Co. v. Pribyl*, 259 F.3d 587, 602 n. 4 (7th Cir. 2001) (citing *Dorr v. Sacred Heart Hosp.*, 228 Wis.2d 425, 456-57, 597 N.W.2d 462 (1999)).

Breckenridge argues that "the evidence shows that Schwarz engaged in a national, focused, effort to meet with suppliers, customers, and others, to promote Schwarz's NULEV product while simultaneously making false statements to induce others not to buy or dispense NEOSOL." (Breckenridge Brief in Opposition to Schwarz's Motion for Summary Judgment on Breckenridge's Counterclaims, p. 3) However, Breckenridge fails to cite this "evidence." Instead, Breckenridge relies on allegations and "strong inferences," which are insufficient to overcome a motion for summary judgment. The only evidence that is properly before this court is the Losiniecki deposition testimony. Moreover, this court has concluded that the Losiniecki statements set forth in the deposition transcript regarding pending litigation were not false, and there is no evidence that those statements were made with the intent to interfere.

Finally, sections 100.18(1) and 100.182(2) of the Wisconsin statutes require an untrue, deceptive or misleading advertisement, announcement, statement or representation. Beyond the inadmissible Rebecca Recard statements and the Losiniecki deposition testimony, Breckenridge has failed to produce any evidence of untrue, deceptive or misleading statements. The counterclaims will be dismissed.

The court notes that Breckenridge requested a continuance under Rule 56(f) to gather more evidence in support of its counterclaims. However, Breckenridge has failed

to clearly set forth its basis for a continuance. Given the length of time that this case has been pending, the multiple extensions on the discovery deadline, a discovery cutoff of December 20, 2004, and the age of the alleged "pattern and scheme," it is remarkable that Breckenridge has not filed any motion to reopen its briefing or submitted additional evidence.

Now, therefore,

IT IS ORDERED that Schwarz Pharma, Inc.'s, motion for partial summary judgment is denied.

IT IS FURTHER ORDERED that Breckenridge Pharmaceutical, Inc.'s, motion for summary judgment is granted as to Count I. The motion is denied as to all other counts.

IT IS FURTHER ORDERED that Schwarz Pharma, Inc.'s, motion for summary judgment on Breckenridge's counterclaims is granted.

IT IS FURTHER ORDERED that Breckenridge Pharmaceutical, Inc.'s, request for a continuance is denied.

Dated at Milwaukee, Wisconsin, this 15th day of September, 2005.

BY THE COURT

s/ C. N. CLEVERT, JR.
C. N. CLEVERT, JR.
U. S. District Judge